



Medical Necessity Criteria for Osteoporosis Agents

Drug Class - Osteoporosis Agents. This drug class includes multiple agents primarily used in the treatment of osteoporosis. Currently four subclasses of agents are used in the treatment of osteoporosis: bisphosphonates, selective estrogen receptor modulators (SERMs), parathyroid hormone 1-34 amino acids (PTH), and calcitonins.

Bisphosphonates:

- Alendronate (Fosamax) & Alendronate plus D (Fosamax plus D)
- Alendronate effervescent tablet (Binosto)
- Ibandronate (Boniva)
- Risedronate (Actonel) & risedronate plus calcium (Actonel with Calcium)
- Risedronate sodium (Atelvia)

SERMs:

- Raloxifene (Evista)

PTH:

- Teriparatide (Forteo)

Calcitonins:

- Calcitonin-salmon (Miacalcin)
- Recombinant calcitonin (Fortical)

Background - After evaluating the relative clinical and cost effectiveness of the osteoporosis agents, the DoD P&T Committee recommended that the following medications be designated as non-formulary. This recommendation has been approved by the Director, DHA.

- Calcitonin-salmon (Miacalcin)
- Alendronate effervescent tablet (Binosto)

Effective Date: 26 November 2008, 16 April 2014

Patients currently using non-formulary agents may wish to ask their doctor to consider a formulary alternative.

Special Notes:

1. Active duty cost share always \$0 in all points of service for all three tiers; TRICARE does not cover non-formulary medications for active duty service members unless they are determined to be medically necessary.
2. MTFs will be able to fill non-formulary requests for non-formulary medications only if both of the following conditions are met: 1) a MTF provider writes the prescription, and 2) medical necessity is established for the non-formulary medication. MTFs may (but are not required to) fill a prescription for a non-formulary medication written by a non-MTF provider to whom the patient was referred, as long as medical necessity has been established.

Medical Necessity Criteria for Osteoporosis Agents

The non-formulary cost share for calcitonin-salmon (Miacalcin) may be reduced to the formulary cost share if the patient meets any of the following criteria.

1. Use of Fortical, the formulary alternative is contraindicated (e.g., due to hypersensitivity).
2. The patient has experienced or is likely to experience significant adverse effects from Fortical, the formulary alternative.
3. Use of Fortical, the formulary alternative has resulted in therapeutic failure.
 - The patient previously responded to Miacalcin and changing to a uniform formulary agent would incur unacceptable risk.

The non-formulary cost share for alendronate effervescent tablet (Binosto) may be reduced to the formulary cost share if the patient meets the following criteria.

1. The patient cannot swallow tablets or cannot consume 8 oz of water and has no sodium restrictions.

Criteria approved through the DoD P&T Committee process

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Defense Health Agency,
a component of the [Military Health System](#)
7700 Arlington Blvd,
Falls Church, VA 22042



TRICARE Pharmacy Program Medical Necessity Form for
alendronate effervescent tablet (Binosto)



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This form applies to the TRICARE Pharmacy Program (TPharm). The medical necessity criteria outlined on this form also apply at Military Treatment Facilities (MTFs). The form must be completed and signed by the prescriber.

- Alendronate [Fosamax, generics], Fosamax Plus D, ibandronate tablet [Boniva tablet, generics], and Actonel [risedronate immediate-release] are the formulary bisphosphonate osteoporosis agents on the DoD Uniform Formulary. Alendronate effervescent tablet (Binosto) is non-formulary but available to most beneficiaries at the non-formulary cost share.
- You do NOT need to complete this form in order for non-Active duty beneficiaries (spouses, dependents, and retirees) to obtain non-formulary medications at the non-formulary cost share. The purpose of this form is to provide information that will be used to determine if the use of a non-formulary medication is medically necessary. If a non-formulary medication is determined to be medically necessary, non-Active duty beneficiaries may obtain it at the formulary cost share.
- Active duty service members may not fill prescriptions for a non-formulary medication unless it is determined to be medically necessary. There is no cost share for active duty service members at any DoD pharmacy point of service.

MAIL ORDER and RETAIL	<ul style="list-style-type: none">The provider may call: 1-866-684-4488 or the completed form may be faxed to: 1-866-684-4477The patient may attach the completed form to the prescription and mail it to: Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954 or email the form only to: TPharmPA@express-scripts.com	MTF	<ul style="list-style-type: none">Non-formulary medications are available at MTFs only if both of the following are met:<ul style="list-style-type: none">The prescription is written by a military provider or, at the discretion of the MTF, a civilian provider to whom the patient was referred by the MTF.The non-formulary medication is determined to be medically necessary.Please contact your local MTF for more information. There are no cost shares at MTFs.
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Step 1 Please complete patient and physician information (please print):

Patient Name:	_____	Physician Name:	_____
Address:	_____	Address:	_____
Sponsor ID #	_____	Phone #:	_____
Date of Birth:	_____	Secure Fax #:	_____

Step 2 Please explain why the patient cannot be treated with all of the formulary medications.

Please explain why the patient cannot be treated with the formulary medications. Circle the reason code if applicable. You MUST supply a specific written clinical explanation as to why each of the formulary medications would be unacceptable.

Formulary Medication	Reason	Clinical Explanation
Alendronate [Fosamax, Fosamax Plus D, generics]	1	
Ibandronate tablet [Boniva tablet, generics]	1	
Actonel [risedronate immediate-release], Actonel with Calcium]	1	

Acceptable clinical reasons for not using the formulary medications are:

- The patient cannot swallow tablets or cannot consume 8 oz of water and has no sodium restrictions.

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

Prescriber Signature

Date